

EXHIBIT 9

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CENTRAL DISTRICT OF CALIF.
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FILED

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15 UNITED STATES DISTRICT COURT
16 CENTRAL DISTRICT OF CALIFORNIA
17 WESTERN DIVISION

19 CENTOCOR, INC.,

20 Plaintiff,

21 v.

22 GENENTECH, INC. and CITY OF
HOPE NATIONAL MEDICAL
23 CENTER ,

24 Defendants.

Case No. CV 08-03573 PA

COMPLAINT FOR
DECLARATORY JUDGMENT

(AGRx)

26 Plaintiff Centocor, Inc. ("Centocor"), for its complaint, alleges as
27 follows:
28

NATURE OF THE CASE

2 1. In this action, Centocor seeks a declaration that U.S. Patent
3 'No. 6,331,415 (the "Cabilly II patent") is invalid, unenforceable and/or not infringed
4 by Centocor's abciximab and ustekinumab antibody products.

THE PARTIES

7 2. Centocor is a corporation organized under the laws of the
8 Commonwealth of Pennsylvania with a principal place of business in Horsham,
9 Pennsylvania.

11 3. On information and belief, Genentech, Inc. (“Genentech”) is a
12 Delaware corporation with its principal place of business in South San Francisco,
13 California.

15 4. On information and belief, City of Hope National Medical Center
16 (“City of Hope”) is a California not-for-profit organization with its principal place of
17 operation in Duarte, California.

19 5. On information and belief, Genentech and City of Hope are co-
20 assignees of the Cabilly II patent.

JURISDICTION AND VENUE

23 6. This action arises under the Declaratory Judgment Act, Title 28 of
24 the United States Code, Chapter 151, for the purpose of determining an actual and
25 justiciable controversy between the parties hereto. The Court has subject matter
26 jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

1 7. This Court has personal jurisdiction over Genentech based on its
2 principal place of business in California. This Court has personal jurisdiction over
3 City of Hope based on its organization under the laws of the state of California and
4 because its principal place of operation is in California.

6 8. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b),
7 (c), and (d).

THE CABILLY PATENTS

10 9. On April 8, 1983, Shmuel Cabilly, Herbert Heyneker, William
11 Holmes, Arthur Riggs and Ronald Wetzel (the “Cabilly Applicants”) filed a patent
12 application in the United States Patent and Trademark Office (“PTO”) that issued on
13 March 28, 1989, as U.S. Patent No. 4,816,567 (the “Cabilly I patent”). On
14 information and belief, the Cabilly Applicants assigned their rights to Genentech
15 and/or City of Hope.

17 10. On the same day that the Cabilly I patent issued, U.S. Patent
18 No. 4,816,397 (the “Boss patent”) issued to Michael Boss, John Kenten, John Emtage
19 and Clive Wood (the “Boss Applicants”). On information and belief, the Boss
20 Applicants assigned their rights to Celltech Therapeutics Limited (“Celltech”).
21 Celltech is a British company with its principal place of business in Slough, England.

23 11. At the time that the Boss and Cabilly I patents issued, the Cabilly
24 Applicants had a continuation application pending in the PTO (the “Cabilly II
25 application”). The Cabilly Applicants copied claims from the Boss patent in order to
26 provoke the PTO Board of Patent Appeals & Interferences to initiate an interference
27 proceeding to determine priority – i.e., to determine whether it was the Cabilly
28 Applicants or the Boss Applicants who had made the purported invention first.

1 12. In February 1991, the PTO Board declared a patent interference
2 between the pending Cabilly II application and the Boss patent on the basis that both
3 claimed the same purported invention.

4
5 13. After years of adversarial proceedings in the PTO, in August
6 1998, the PTO Board found that the Boss patent was entitled to priority over the
7 Cabilly II application. The Final Decision indicated that the Cabilly Applicants were
8 “not entitled to a patent . . .”

9
10 14. In October 1998, Genentech filed a civil action to appeal the
11 decision of the PTO Board awarding priority to the Boss patent (Genentech, Inc. v.
12 Celltech Ltd., Case no. C98-3926 (N.D. Cal.)). In March 2001, the parties to that
13 action filed a notice of settlement and joint request for entry of settlement
14 instruments. As part of their settlement, the parties asked the district court to find
15 that Genentech won the priority contest. The district court then issued an order
16 directing the PTO to vacate its determination that the Boss Applicants were entitled
17 to priority, to revoke the Boss patent, and to issue a patent on the Cabilly II
18 application.

19
20 15. After the district court issued its order to the PTO, the PTO
21 referred the Cabilly II application to an examiner for further action, including
22 consideration of materials previously submitted to the PTO that had not clearly been
23 considered by the examiner.

24
25 16. One of the papers submitted by the Cabilly Applicants prior to
26 declaration of the interference was an Information Disclosure Statement that
27 identified, among other references, Valle et al., Nature, 300:71-74 (1982). In its
28 Information Disclosure Statement, the Cabilly II Applicants characterized this

1 reference as being cited as part of a group of references identified “in the interests of
2 good order” because it was cited during prosecution of the Cabilly I application. The
3 Cabilly Applicants also expressly represented that the Valle (1982) work “is readily
4 distinguishable from the instant claims in that the oocytes are not transformed with
5 DNA, but instead are used to transiently express mRNA preparations.” (Sept. 18,
6 1991 IDS at page 2). This Information Disclosure Statement was signed by a
7 representative of Genentech. This representation, however, contradicted a
8 representation Genentech had made about the Valle (1982) reference when it was
9 opposing Celltech’s European Boss patent.

10

11 17. During the time that Genentech and Celltech were involved in the
12 interference proceeding, Genentech submitted an opposition to Celltech’s European
13 patent (EP-B-0120694), the European patent corresponding to the Boss patent. The
14 claims in the Celltech European Boss patent and the claims in the Cabilly II
15 application were both directed, *inter alia*, to processes for producing a heterologous
16 Ig molecule in a single host cell comprising transforming the host cell with separate
17 DNA sequences encoding polypeptide chains comprising at least the variable
18 domains of the heavy and light chains and then expressing those chains separately in
19 the transformed host cell.

20

21 18. As part of the grounds for opposition in the European proceeding,
22 Genentech identified the Valle (1982) publication as a reference that anticipated the
23 Boss European patent. Contrary to the characterization of this reference during the
24 Cabilly II application prosecution, Genentech specifically represented to the
25 European Patent Office that Valle (1982):

26 clearly teaches the production of an immunologically
27 functional heterologous immunoglobulin molecule in
28 eukaryotic cells transfected by separate DNA molecules

1 encoding its heavy and light chains, respectively. In view
2 of the broad implications evidenced by the Abstract, the
3 fact that the actual experiment was performed with
4 microinjected mRNAs is not relevant. In any event,
5 because the messenger RNA carries the information from
6 DNA to the ribosomal sites of protein synthesis, it is
7 functionally equivalent to DNA.

8

9 19. Thus, when it was in its interest to do so during its opposition to
10 Celltech's European Boss patent, Genentech took the position that the Valle (1982)
11 reference clearly teaches the production of an immunologically functional
12 heterologous immunoglobulin molecule in eukaryotic cells transfected by separate
13 DNA molecules encoding its heavy and light chains, whereas during the prosecution
14 of the Cabilly II application, it was asserted that the Valle (1982) reference was
15 "readily distinguishable" because the oocytes were not transformed with DNA.

16

17 20. The Valle (1982) reference was, by Genentech's own assertions,
18 material to the patentability of at least some of the subject matter common to the
19 Cabilly II application and Boss patent claims. But the Cabilly Applicants did not
20 advise the Examiner that Genentech had relied upon this Valle (1982) reference in
21 opposing the Boss European patent, nor did it advise the Examiner of the contrary
22 positions that it had taken in the European opposition proceeding with respect to the
23 teachings of the Valle (1982) reference.

24

25 21. The Information Disclosure Statement submitted by the Cabilly
26 Applicants prior to declaration of the interference also identified, among other
27 references, Rice et al., Proc. Natl. Acad. Sci. 77:7862-7865 (1982). In its
28 Information Disclosure Statement, the Cabilly II Applicants characterized this

1 reference as being cited as part of a group of references identified “in the interests of
2 good order” because it was cited during prosecution of the Cabilly I application and
3 indicated that they were not providing a copy of this reference.

4

5 22. The citation provided to the PTO was, however, in error. When
6 opposing the Celltech European Boss patent, Genentech cited Rice et al., Proc. Natl.
7 Acad. Sci. 79:7862-7865 (1982), and argued that the subject matter of the European
8 Boss patent did not involve an inventive step over this disclosure in view of other
9 references.

10

11 23. Thus, although the Rice (1982) reference was, by Genentech’s
12 own assertions, material to the patentability of at least some of the subject matter
13 common to the Cabilly II application and Boss patent claims, the Cabilly Applicants
14 did not advise the Examiner that: (a) Genentech had relied upon this Rice (1982)
15 reference in opposing the Boss European patent; (b) that Genentech argued that the
16 Boss European patent did not involve an inventive step in view of this and other
17 references; or (c) that it had mis-cited this reference in its Information Disclosure
18 Statement. This information was material to the prosecution of the Cabilly II patent.

19

20 24. Also, during this post-interference and post-district court action
21 prosecution of the Cabilly II application (the “post-proceeding prosecution”), the
22 Cabilly Applicants submitted a substantial amount of material to the PTO, including
23 listings of numerous pleadings from the litigation as well as numerous prior art
24 references. Pursuant to the express provisions of the Manual of Patent Examining
25 Procedure, submission of such long lists should be avoided but, if necessary, then
26 Applicants are directed to “highlight” the documents known to be of most
27 significance. MPEP 2004(13). The Cabilly II Applicants did not do so.

1 25. Although the Cabilly II Applicants dumped numerous references
2 on the PTO, they failed to identify critical prior art, including U.S. Patent
3 No. 4,399,216, issued to Axel et. al. on August 16, 1983, assigned on its face to The
4 Trustees of Columbia University (the “216 patent”). On information and belief, the
5 ‘216 patent was known to Genentech, and its materiality to the Cabilly II claims and
6 recombinant production of antibodies in general was known to Genentech, at least
7 based on the fact that Genentech had taken a license of this patent for which it paid
8 substantial royalties.

9

10 26. The Cabilly II patent issued on December 18, 2001, and is
11 assigned on its face to Genentech. The Cabilly II patent is presently under
12 Reexamination (Control No. 90/007,542) at the PTO, where all claims of the
13 Cabilly II patent are currently under final rejection. The bases for rejection include
14 obviousness-type double patenting.

15

16 27. That the Rice (1982) reference is material to the patentability of
17 the Cabilly II patent claims is confirmed by the fact that it is has been relied upon by
18 the PTO in rejecting the Cabilly II patent claims during the reexamination
19 proceeding.

20

21 28. That the '216 patent is material to the patentability of the
22 Cabilly II patent claims is confirmed by the fact that it is has been relied upon by the
23 PTO in rejecting the Cabilly II patent claims during the reexamination proceeding.

24

25 29. The foregoing provides examples of actions demonstrating that,
26 during examination of the Cabilly II Application, while under a duty of candor to the
27 PTO, Genentech and/or the Cabilly Applicants intended to mislead the PTO and did
28 not act in good faith in dealing with the PTO. Intent can be inferred at least from the

1 fact that Genentech failed to disclose statements and references which, by its own
2 assertions in the Boss European Opposition proceedings, were material to the
3 patentability of the Cabilly II application claims.

4

5 THE LICENSE AGREEMENTS

6 **Abciximab (ReoPro®)**

7 30. On December 5, 1994, Centocor entered into an Agreement with
8 Genentech under which it received, inter alia, a license under the Cabilly I patent and
9 under the application which ultimately issued as the Cabilly II patent to make, have
10 made, use, and sell substances capable of binding to the GPIIb IIIa receptor which,
11 but for the license, would infringe one or more claims of the patents (the "Genentech
12 Agreement"). Centocor has paid, and Genentech has accepted, royalties on sales of
13 abciximab, an antibody fragment which binds to the glycoprotein GPIIb IIIa of
14 human platelets and inhibits platelet aggregation.

15

16 31. There is an actual and justiciable controversy between Centocor,
17 Genentech and City of Hope with respect to whether making, using and selling
18 abciximab infringes any valid and enforceable claim of the Cabilly II patent.

19

20 **Infliximab (Remicade®)**

21 32. On March 31, 1998, Centocor entered into a Patent License
22 Agreement with Celltech under which it received, inter alia, a non-exclusive
23 sublicense under the "Genentech Licensed Patents," which included the Cabilly I
24 patent and any patents maturing from applications that were continuations of the
25 Cabilly I patent, which includes the later-issued Cabilly II patent (the "Celltech
26 Agreement"). This was a license to develop, make, have made, use and sell a
27 pharmaceutical product containing a recombinant engineered antibody or antibody
28 fragment capable of binding specifically to TNF-alpha, being both the product later

1 marketed by Centocor as infliximab (Remicade®) and one additional product whose
2 research and development was conducted under the direction of Centocor by itself or
3 in collaboration with a third party.

4

5 33. On information and belief, at least a portion of the royalties that
6 Centocor pays to Celltech based on its infliximab (Remicade®) product are passed
7 through to Genentech and/or City of Hope.

8

9 **Ustekinumab (CNTO-1275)**

10 34. Ustekinumab (CNTO 1275) is a new, human monoclonal
11 antibody developed by Centocor which targets the cytokines interleukin-12 (IL-12)
12 and interleukin-23 (IL-23), naturally occurring proteins that are important in
13 regulating immune responses and that are thought to be associated with some
14 immune-mediated inflammatory disorders, including psoriasis.

15

16 35. All Phase III clinical trials believed necessary to support an
17 application for approval to sell ustekinumab in the United States have been
18 completed. In February 2008, the Biologics License Application (BLA) for
19 ustekinumab (CNTO 1275) was accepted for review by the U.S. Food and Drug
20 Administration for the treatment of chronic moderate-to-severe plaque psoriasis in
21 adults. Centocor expects to obtain regulatory approval to market and sell
22 ustekinumab in the United States within the next year.

23

24 36. Centocor has been making substantial preparations to market and
25 sell ustekinumab in the United States upon receipt of regulatory approval to do so. It
26 has hired and been training key management, support and sales personnel to market
27 and sell ustekinumab; retaining outside consultants and vendors to assist in its
28 marketing and sale of ustekinumab in the United States; has retained suppliers and

1 advertising agencies to prepare for the launch of the product; has prepared
2 promotional materials for the launch of the product; has initiated planning for medial
3 affairs and pharmacovigilance activities associated with the marketing of the product;
4 has built supply capacity; and is completing manufacturing and distribution launch
5 preparations.

6

7 37. Genentech has advised Centocor that its existing licenses would
8 not cover the marketing and sale of ustekinumab and has acknowledged that
9 Centocor will need an additional license from Genentech under the Cabilly II patent
10 for ustekinumab. There is an actual and justiciable controversy between Centocor,
11 Genentech, and City of Hope with respect to whether Centocor's making, using and
12 selling of ustekinumab will infringe any valid and enforceable claim of the Cabilly II
13 patent.

14

15 **FIRST CAUSE OF ACTION**

16

17 **PATENT INVALIDITY**

18

19 38. Centocor incorporates the allegations of paragraphs 1-37 as if
20 fully set forth herein.

21

22 39. An actual controversy has arisen and now exists between the
23 parties concerning the validity of the Cabilly II patent.

24

25 40. The Cabilly II patent is invalid because it is anticipated and/or
26 obvious under 35 U.S.C. §§ 102 and 103.

27

28 41. The Cabilly II patent is invalid based on the judicially created
29 doctrine of obviousness type double patenting and/or under 35 U.S.C. §§ 101 and/or
30 103.

1 42. The Cabilly II patent is invalid under 35 U.S.C. § 112.
2
3

4 43. Centocor hereby seeks a declaratory judgment that the Cabilly III
5 patent is invalid under 35 U.S.C. §§ 101, 102, 103, 112, *et seq.* and/or under the
6 judicially created doctrine of obviousness type double patenting.
7
8

SECOND CAUSE OF ACTION
PATENT UNENFORCEABILITY

9 44. Centocor incorporates the allegations of paragraphs 1-37 as if
10 fully set forth herein.
11
12

13 45. An actual controversy has arisen and now exists between the
14 parties concerning the enforceability of the Cabilly II patent.
15
16

17 46. The Cabilly II patent is unenforceable due to inequitable conduct
18 before the PTO. Such conduct includes, but is not limited to, hiding critical
19 references, failing to act with candor regarding the significance of certain prior art,
20 and failing to advise the PTO of positions taken by Genentech in European patent
21 proceedings that were inconsistent with representations made during prosecution of
22 the Cabilly II Application. On information and belief, the Cabilly Applicants and/or
23 Genentech withheld this material information and made these material
24 representations with intent to deceive the patent examiner.
25
26

27 47. Centocor hereby seeks a declaratory judgment that the Cabilly II
28 patent is unenforceable due to inequitable conduct.
29
30

THIRD CAUSE OF ACTION

NON-INFRINGEMENT

3 48. Centocor incorporates the allegations of paragraphs 1-31 and 34-
4 37 as if fully set forth herein.

6 49. An actual controversy has arisen and now exists between the
7 parties concerning whether Centocor's abciximab or ustekinumab antibody products
8 infringe any valid and enforceable claim of the Cabilly II patent.

10 50. Centocor seeks a declaratory judgment that its making, using and
11 selling of its abciximab and ustekinumab antibody products does not and will not
12 infringe any valid and enforceable claim of the Cabilly II patent.

FOURTH CAUSE OF ACTION

CENTOCOR OWES NO ROYALTIES

16 51. Centocor incorporates the allegations of paragraphs 1-37 as if
17 fully set forth herein.

19 52. An actual controversy has arisen and now exists between the
20 parties concerning whether Centocor is entitled to recoup royalties paid to Genentech
21 if the Cabilly II patent is deemed to be unenforceable. “Licensed Products” is
22 defined in the Genentech Agreement to include products that would, if not licensed,
23 infringe one or more claims of the Cabilly II patent “which have neither expired nor
24 been held invalid by a court or other body of competent jurisdiction from which no
25 appeal has been or may be taken.” Because invalidity and unenforceability are
26 distinct concepts under U.S. Patent laws, the License Agreement does not require
27 Centocor to pay Genentech royalties on an unenforceable patent. Accordingly,
28 Centocor is entitled to a declaratory judgment that Genentech must repay Centocor

1 the amounts Centocor paid to Genentech under the Genentech License Agreement
2 based on the Cabilly II patent if that patent is declared to be unenforceable.

4 53. An actual controversy has arisen and now exists between the
5 parties concerning whether Centocor is entitled to recoup royalties paid to Celltech
6 and passed through to Genentech and/or City of Hope if the Cabilly II patent is
7 deemed to be invalid or unenforceable. Issues relating to the validity, construction
8 and performance of the Celltech Agreement are governed by English law. The
9 Cabilly II patent may, in accordance with principles of English law, be declared to
10 have been invalid ab initio. Accordingly, Centocor is entitled to a declaratory
11 judgment that Genentech and/or City of Hope must repay Centocor the amounts
12 Celltech passed through under the Celltech Agreement based on Centocor's
13 infliximab (Remicade®) product if the Cabilly II patent is declared to be invalid or
14 unenforceable.

PRAYER FOR RELIEF

17 WHEREFORE, Plaintiff Centocor requests that judgment be entered in
18 favor of Centocor and against Defendants:

- 20 1. Declaring that the Cabilly II patent is invalid;

21

22 2. Declaring that the Cabilly II patent is not enforceable;

23

24 3. Declaring that Centocor's abciximab and ustekinumab products

25 do not infringe any valid and enforceable claim of the Cabilly II patent;

26

27 4. Awarding Centocor damages at least equivalent to any unjust

28 enrichment enjoyed by Genentech and/or City of Hope;

1 5. Awarding Centocor damages at least equivalent to any amounts
2 received by Genentech and/or City of Hope as royalties or other license fees due on
3 account of the Cabilly II patent;

5 6. Enjoining Genentech and City of Hope from enforcing the
6 Cabilly II patent;

8 7. Awarding Centocor its costs and attorneys' fees; and

10 8. Awarding Centocor such other and further relief as the Court
11 may deem just and proper under the circumstances.

13 | Dated: May 30, 2008

SHEPPARD, MULLIN, RICHTER & HAMPTON LLP

By

Gary A. Clark

Attorneys for Plaintiff
CENTOCOR, INC.